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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738

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EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1794	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,059	SCHOENLE ET AL.	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74,76-84,86-91 and 130-133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,76-84,86-91 and 130-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Request for Reconsideration filed September 25, 2007 has been received and considered by Examiner.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 102 rejection of claims 84, 86, 88, 89, 91, 132 and 133 made of record in paragraph 3 of the previous Office Action mailed August 1, 2007 has been withdrawn due to Applicant's argument presented on page 3 of the Request for Reconsideration filed September 25, 2007 regarding the 35 U.S.C. 102 rejection of claims 84, 86, 88, 89, 91, 132 and 133.

3. The 35 U.S.C. 103 rejections of claims 79, 83, 87 and 90 made of record in paragraphs 4 and 5 of the previous Office Action mailed August 1, 2007 have been withdrawn due to Applicant's argument presented on page 3 of the Request for Reconsideration filed September 25, 2007 regarding the 35 U.S.C. 102 rejection of claims 84, 86, 88, 89, 91, 132 and 133.

REPEATED REJECTIONS

Claim Rejections - 35 USC § 102

4. The 35 U.S.C. 102 rejection of claims 74, 76-78 and 80-82 made of record in paragraph 2 of the previous Office Action mailed August 1, 2007 has been repeated for the reasons previously made of record.

Claim Rejections - 35 USC § 103

5. The 35 U.S.C. 103 rejection of claims 130 and 131 made of record in paragraph 6 of the previous Office Action mailed August 1, 2007 has been repeated for the reasons previously made of record.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

6. Claims 84, 86, 88, 89, 91, 132 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgmeier (USPN 6,200,290).

In regard to claims 84 and 88, Burgmeier teaches a component of a medical device (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64), where the component includes a region that comprises a polyamide (for example, PEBAX 6333) having a hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1), where the region of the component is tube-shaped (Fig. 1) (see rest of document for more embodiments comprising a polyamide each having a hoop stress that is greater than 3300 psi).

In regard to claim 86, Burgmeier teaches that the component is a catheter (col. 1, lines 10-31).

In regard to claims 89 and 91, Burgmeier et al. teaches a tube-shaped portion of a catheter where the tube-shaped portion includes a region (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64) that comprises a polyamide (for example, PEBAX 6333) having a hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1) (see rest of document for more embodiments comprising a polyamide each having a hoop stress that is greater than 3300 psi).

In regard to claims 132 and 133, all PEBAX polyamides, including (for example, PEBAX 6333) is a copolymer.

Claim Rejections - 35 USC § 103

7. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Burgmeier (USPN 6,200,290).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed in regard to claims 74 and 80 in the previous Office Action. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21).

Pinchuk et al. fail to teach that the balloon has a hoop stress of at least about 3300 psi.

Burgmeier teaches a balloon (col. 1, lines 10-31 and lines 43-45, col. 1, line 52-col. 2, line 34 and col. 3, lines 17-64) that includes a region that comprises a polyamide (for example, PEBAX 6333) having a hoop stress of (for example) 24,112 psi (Table I, col. 5 and 6, Balloon No. 1). Therefore, one of ordinary skill in the art would have recognized to have used the material comprising a polyamide that has a hoop stress of (for example) 24,112 psi taught by Burgmeier as the polyamide of the balloon of Pinchuk et al. since a polyamide that has a hoop stress of 24,112 psi (and similar values [see rest of document for more embodiments comprising a polyamide]) is a well known suitable material for use as the material of a catheter balloon as taught by Burgmeier.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the material comprising a polyamide that has a hoop stress of (for example) 24,112 psi taught by Burgmeier as the polyamide of the balloon of Pinchuk et al. since a polyamide that has a hoop stress of 24,112 psi (and similar values [see rest of document for more embodiments comprising a polyamide]) is a well known suitable material for use as the material of a catheter balloon as taught by Burgmeier.

8. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgmeier (USPN 6,200,290) in view of Pinchuk et al. (USPN 6,110,142).

In regard to claim 87, Burgmeier teaches the component as discussed above.

Burgmeier fails to teach that the component comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the component of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the balloon of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

In regard to claim 90, Burgmeier teaches the tube shaped portion as discussed above.

Burgmeier fails to teach that the tube shaped portion comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the tube shaped portion of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the tube shaped portion of Burgmeier with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

Response to Arguments

9. Applicant's arguments presented on pages 1-2 of the Request for Reconsideration regarding the 35 U.S.C. 102 rejection of claims 74, 76-78 and 80-82 have been fully considered but are not persuasive.

Applicant argues that Pinchuk does not anticipate claims 74, 76-78 and 80-82 because "[i]t is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the tensile strength defined in Applicants' specification...". The word "calculated" immediately prior to "tensile strength" (col. 11, line 19 of Pinchuk) does not change

the meaning of "tensile strength" ("calculated tensile strength" is no different from "tensile strength"). The adjective "calculated" is used merely because the tensile strength is calculated from two different values. Applicant calculates tensile strength from two different values: load at break and cross-sectional area (page 10, line 30-page 11, line 2). Applicant's specification states that the tensile strength "is determined by dividing the load at break... by the cross-sectional area...". Page 10, line 30-page 11, line 2. "[D]ividing the load at break... by the cross-sectional area" is a calculation. Therefore, Applicant's tensile strength can reasonably be called a "calculated" tensile strength. Regardless, as stated above, the word "calculated" immediately prior to "tensile strength" (col. 11, line 19 of Pinchuk) does not change the meaning of "tensile strength".

10. Applicant's arguments presented on pages 3-5 of the Request for Reconsideration regarding the 35 U.S.C. 103 rejections of claims 79, 83, 87 and 90 are moot due the withdrawal of these rejections in this Office Action for the reason provided above.

11. Applicant's arguments presented on page 6 of the Request for Reconsideration regarding the 35 U.S.C. 103 rejection of claims 130 and 131 have been fully considered but are not persuasive. Applicant's arguments here depend entirely upon Applicant's arguments regarding the 35 U.S.C. 102 rejection of claims 74, 76-78 and 80-82, which have been addressed above.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris, can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter B. Aughenbaugh
12/08/07

12/08/07